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TITLE: Deployment-Related Mild Traumatic Brain Injury (mTBI): Incidence, Natural History, and Predictors of Recovery in Soldiers Returning from OIF/OEF

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14. ABSTRACT The overarching aim of this study is to describe the epidemiology, natural history, and prognostic predictors of mild traumatic brain injury (mTBI) in a well-defined cohort of 1,500 recently-deployed soldiers at Fort Carson and Fort Bragg. Mild traumatic brain injury is a frequent injury in theatre and there are substantial gaps in our understanding of the recovery patterns after this injury and whether currently used mTBI screening tools are valid. This study is augmenting ongoing surveillance and clinical efforts at these locations by expanding the post-deployment assessment of traumatic brain injury (TBI) and TBI-related exposures; identifying pre-existing and deployment-related exposures and comorbid conditions that may influence the risk or prognosis of mTBI-related sequelae; determining the relationship of mTBI on screens with clinical interviews, and re-assessing this cohort at three, six, and twelve months after return from deployment with the aim of determining the persistence of post-deployment symptoms and the degree to which these impact on military or civilian employment, including fitness for military duty, functional status, and quality of life.					
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Table of Contents

	Page
Introduction	1
Body	1-4
Key Research Accomplishments	4
Reportable Outcomes	4
Conclusion	4-5
References	5
Appendix	6-8
Supporting Data	6-8

Introduction

The overarching aim of this study is to describe the epidemiology, natural history, and prognostic predictors of mild traumatic brain injury (mTBI) in a well- defined cohort of 1,500 recently- deployed soldiers at Fort Carson and Fort Bragg. Mild traumatic brain injury is a frequent injury in theatre and there are substantial gaps in our understanding of the recovery patterns after this injury and whether currently used mTBI screening tools are valid. This study is augmenting ongoing surveillance and clinical efforts at these locations by expanding the post-deployment assessment of traumatic brain injury (TBI) and TBI-related exposures; identifying pre-existing and deployment-related exposures and comorbid conditions that may influence the risk or prognosis of mTBI-related sequelae; determining the relationship of mTBI reported on screens with clinical interviews, and re-assessing this cohort at three, six, and twelve months after return from deployment with the aim of determining the persistence of post-deployment symptoms and the degree to which these symptoms impact on military or civilian employment, including fitness for military duty, functional status, and quality of life.

Body

The award was issued effective 1 May 2008. Regulatory reviews were completed on the study protocol for Fort Carson on July 31, 2009, and for Fort Bragg on July 27, 2011. The Fort Carson site has recruited a total of 657 subjects from six cohorts of soldiers returning from OIF/OEF thus far out of the 750 subjects to be recruited. Three month follow-up rates to date are 68%; 6 month follow-up rates are 52%; and 12 month follow-up rates are 45%. The Qualitative Sub-study at the Fort Carson site recruited 103 subjects over two recruitment cohorts, and completed 6 and 12 month follow-ups on those subjects. Six and 12 month follow-up rates for the Qualitative Sub-study are 62% and 59% for Group 1; 27% and 43% for Group 2. The Fort Bragg site has recruited a total of 158 subjects out of the 750 subjects projected. Three month follow-up rates to date are 63%. The Headache sub-study at the Fort Bragg site began shortly after the parent study and has recruited 59 subjects to date.

Both the Qualitative Sub-Study and the Headache Sub-study are leveraging the parent study in order to provide additional evidence in two areas of investigation (determining the added value of acquiring experiential evidence on mild TBI; conducting detailed neurological assessments of Headache, the most common symptom post mild TBI).

Dr. Scher has designed a pilot study of MRIs in subjects with mild TBI, including those with and without headache symptoms during this time period. She is applying for intramural USUHS funds to support the pilot investigation.

Three presentations on the Study were made during this time period. Dr. Lisa Brenner presented preliminary data on TBI data garnered with the Ohio State University structured interview to the June 2011 Federal Interagency TBI Conference (Washington, DC). The talk presented was "Lifetime History of TBI among Returning Service Members and Military Veterans: Bringing together researchers, clinicians, the military and students." 260 of the 345 soldiers included in the preliminary database endorsed criteria for TBI, and reported a total of 622 lifetime TBIs (average number of TBIs reported = 2.39; SD of 1.66). Of the total of 622 TBIs, more than a third (252) were deployment-related. 27% were associated with loss of consciousness. Of the deployment TBIs, the majority were due to blast injuries. Headaches were the primary symptom reported for deployment-related TBIs (26%), and the percent with headache did not vary by cause of injury.

The Fort Bragg team presented an orientation to the study to the Defense and Veterans Brain Injury Center research consortium (researchers across the 19 DVBIC sites).

And, the Fort Bragg team presented the study to several visiting dignitaries, including the Assistant Surgeon General of the Army, Major General Stone, and COL Jamie Grimes during their March visits to the Fort Bragg Traumatic Brain Injury teams.

Dr. Karen Schwab, Study PI, conducted a site visit to the Fort Bragg study site March 6-7, 2012 in order to observe recruitment practices, review protocol adherence, and review standard operating procedures with the study team. The purpose of periodic site visits is to insure study adherence to the protocol, and to standardize study practices across the sites and over time.

In preparation for study data analysis, the team has coordinated analysis plans, updated literature reviews, conducted ongoing quality control of data collection forms at the sites, and designed data bases. A data base manager and data entry clerk were hired in this time period (December, 2011, and February, 2012 respectively) to design the databases, enter, and quality control accumulated study data. Thus far, nearly 6,000 screening tools have been entered into the data base (5,783). Quality control has been conducted on about 50 percent of the entered forms. In addition, agreements with two of the three external military data bases needed to provide complementary data for the study have been obtained. (Defense Manpower Data Center; Armed Forces Health Surveillance Center) The third and final agreement with the Social Security Administration is expected this summer.

Problems in accomplishing tasks: The approval process at Fort Bragg was onerous with the identification of a replacement PI after the reassignment of the original PI to another Army Military Treatment Facility, and IRB requirements for the establishment of Memoranda of Understanding (MOA) for the links to military databases described in the protocol. The MOAs are in process and the IRB has

agreed to review the data merges and related analyses once the MOAs are signed by the appropriate parties. As a result, the study at Fort Bragg was delayed for a period of approximately two years. We requested a one year no-cost extension from the USA Medical Research Acquisition Activity in order to accomplish maximum possible recruitment of the Fort Bragg sample. This was granted 2 August 2011.

Task Reports:

Task 1: IRB approvals:

- Fort Carson has received all approvals (final on July 31, 2009)
- Fort Bragg received all approvals (final on July 27, 2011).

Task 2: Recruitment of Study Personnel

- Fort Carson: Completed
- Fort Bragg: Completed. Subject Recruiter/Research Assistant, and Study Interviewer recruited and trained this report period.
- Headquarters: Completed: Data Manager/analyst, and data entry clerk recruited this report period.

Task 3-4: Study assessments and manuals completed and updated as needed.

Task 5: Training:

Completed with current personnel; new personnel trained as required.
Ohio State Validity Instrument training completed for new personnel.
(Involves several taping of standardized practice interviews; quality control by trainer; additional practice interviews to consolidate standardized interview methodology)

Tasks 6, 8, 9, 11: Recruitment, baseline evaluations, and follow-up interviews:

- Fort Carson: Has enrolled 657 subjects (out of projected 750), and continues to conduct follow-up interviews. Follow-up rate to date is 68% (3 mon); 52% (6 mon); 45% (12 mon)..; Qualitative sub study enrolled 103.
- Fort Bragg: Began recruitment and enrollment of subjects once final regulatory approvals were received July 27, 2011. The site has enrolled 158 subjects since its start date..

Tasks 7 and 10: Interim Reports

- Poster presented at Neurology meetings in April 2011 describing initial findings regarding headache classification, experience of chronic daily headaches and prior diagnosis of migraine.

- Presentation June 2011 at the Federal Interagency Conference on TBI at symposium, “Lifetime History of TBI – Implications for Current Functioning,” Reported preliminary demographic and lifetime TBI incidence for the first 345 subjects. (Slides are attached).
- Interim reports are in preparation to present findings from the Fort Carson cohort (interim reports will be finalized once the Fort Carson cohort recruitment is completed).

Tasks 12-14: Close out of data set and final report: Will be completed at end of the study.

Key Research Accomplishments:

- Deployment mTBI was found to be associated with migraine headaches (Scher et al, 2011)
- Deployment mTBI was found to be associated with chronic daily headaches (Scher et al, 2011)
- Deployment mTBIs were found to account for approximately one-third of lifetime TBIs reported in preliminary analysis. (Brenner et al, 2011)
- Confirming evidence from prior research, deployment mTBIs were primarily due to blast injuries, and Headaches were the most common symptom reported..(Brenner et al, 2011)

Reportable Outcomes:

- Headache Disorders in Recently Deployed Soldiers with and without Traumatic Brain Injury: Poster presentation to the 2011 Annual Meeting of the American Academy of Neurology (April, 2011).
- Successful application and receipt of a Center for Neuroscience and Regenerative Medicine (CNRM) award to expand the study of Headache at the Fort Bragg CDMRP site. The application leveraged the CDMRP award and preliminary data on headache from the study.
- Presentation given on Lifetime History of TBI among Returning Service Members and Military Veterans (June, 2011 at the 2011 Federal Interagency TBI Conference).

Conclusion:

After a substantial delay, Fort Bragg received final regulatory approval and immediately began subject recruitment.. Fort Bragg has enrolled 158 subjects thus far. Fort Carson has enrolled 657 subjects out of their target goal of 750 subjects. A one year no-cost extension will permit recruitment of all subjects for

the baseline surveys and interviews at both sites. Fort Carson is projected to complete all follow-ups for the study, but even with the extension, Fort Bragg will not have sufficient time to complete all follow-ups on all recruited subjects. Both sites have implemented surge support plans in order to maximize recruitment of subjects during large redeployments in order to reach recruitment goals.

Reported on in previous Annual Report: Preliminary analysis of headache data for the study (conducted on a sample size of 174 soldiers with mTBI, and 202 soldier controls) found more migraine and chronic daily headaches in returning soldiers with mTBI. Further, this initial study found that migraine headaches in returning soldiers with mTBI had different patterns of aura-like symptoms. These patterns will be further investigated in the study, as well as with neurological exams supported by separate CNRM funding. Headache is generally identified as the most common sequel of mTBI but its characterization and treatment are not well understood. Continued study can potentially improve future identification of headache patterns associated with mTBI and lead to better and more effective treatment approaches.

Research Presentation during this period of performance: Preliminary analysis of the Ohio State structured interview of TBI found that approximately one-third of lifetime TBIs reported by subjects were deployment injuries. Most of these were from blast injuries. And, the most commonly reported post-TBI symptom was Headache.

References:

A.I. Scher, A. Finkel, H. Terrio, L. Brenner, P. Feit, T. McFate, S. Lewis, K. Schwab, Headache Disorders in Recently Deployed Soldiers with and without Traumatic Brain Injury, Presentation to Annual Meeting of the American Academy of Neurology, April 2011.

L. Brenner, Lifetime History of TBI among Returning Service Members and Military Veterans, Presented to the June 2011 Federal Interagency TBI Conference in Washington, DC

Appendix:

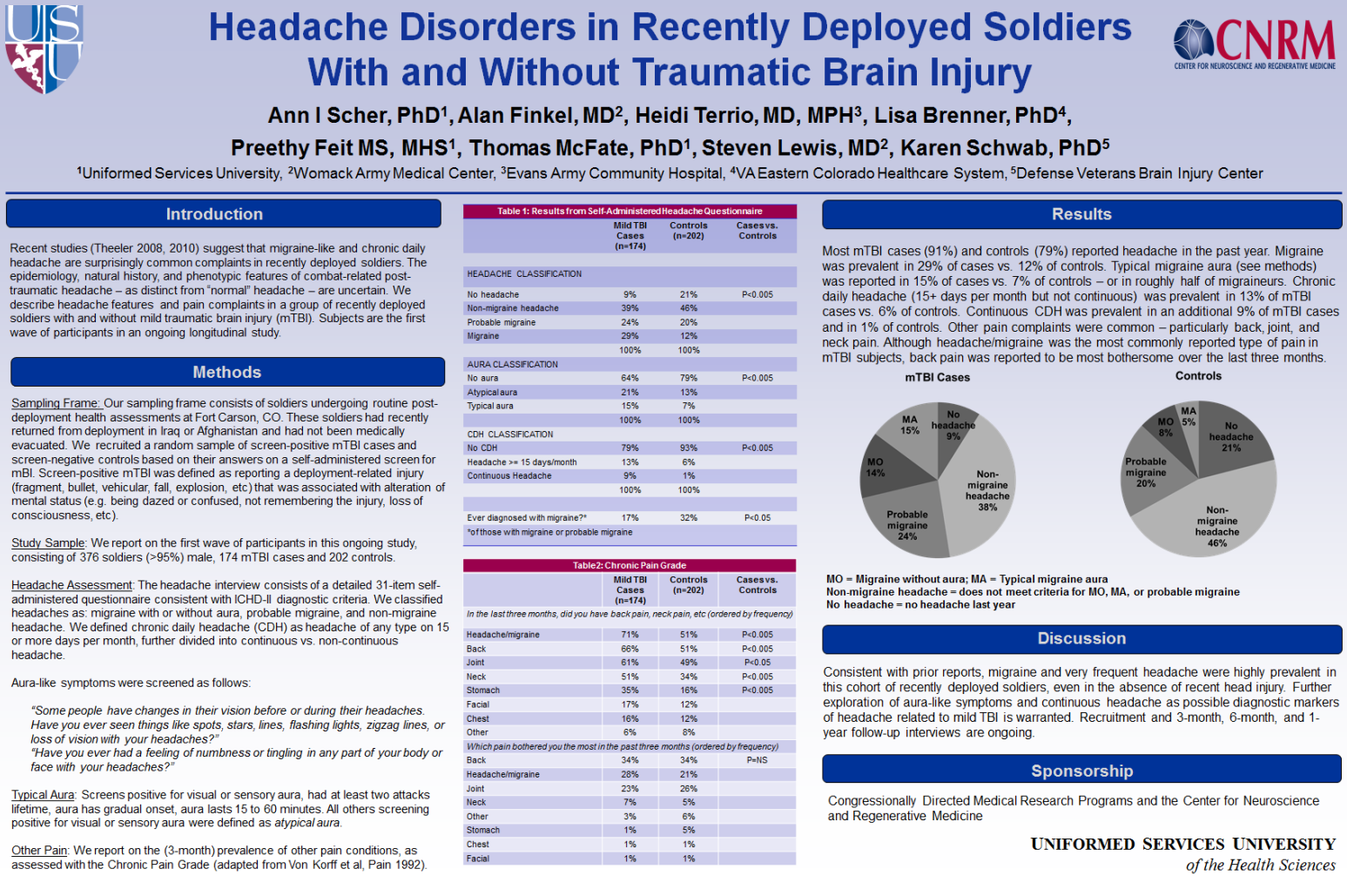
Attachment 1: Poster presented April 2011 at the Annual Meeting of the American Academy of Neurology

Attachment 2: Slides presented June 2011 to the Federal Interagency TBI Conference

Supporting Data

Presented in body of report and in Appendix.

Attachment 1:





Lifetime History of TBI among Returning Service Members and Military Veterans

Lisa Brenner, PhD, ABPP
VISN 19 Mental Illness Research Education
and Clinical Center
University of Colorado,
School of Medicine



Deployment-Related Mild Traumatic Brain Injury (mTBI): Incidence, Natural History, and Predictors of Recovery in Soldiers Returning from OIF/OEF

Study Team:

Lisa Brenner, PhD, ABPP, Lisa Betthausen, MBA,
Heidi Terrio, MD, MPH, Karen Schwab, PhD



Screening – PTSD and TBI – PDHA, DD FORM 2796, JAN 2008

This form must be completed electronically. Handwritten forms will not be accepted.

POST-DEPLOYMENT HEALTH ASSESSMENT (PDHA)

PRIVACY ACT STATEMENT

AUTHORITY: 10 U.S.C. 136, 1074f, 3013, 5013, 8013 and E.O. 9397.

PRINCIPAL PURPOSE(S): To assess your state of health after deployment in support of military operations and to assist military healthcare providers in identifying and providing present and future medical care you may need. The information you provide may result in a referral for additional healthcare that may include medical, dental or behavioral healthcare or diverse community support services.

ROUTINE USE(S): In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, to other Federal and State agencies and civilian healthcare providers, as necessary, in order to provide necessary medical care and treatment. Responses may be used to guide possible referrals.

DISCLOSURE: Voluntary. If not provided, healthcare WILL BE furnished, but comprehensive care may not be possible.

INSTRUCTIONS: Please read each question completely and carefully before entering your response or marking your selection. **YOU ARE ENCOURAGED TO ANSWER EACH QUESTION. ANSWERING THESE QUESTIONS WILL NOT DELAY YOUR RETURN HOME.** Withholding or providing inaccurate information may impair a healthcare provider's ability to identify health problems and refer you to appropriate sources for additional evaluation or treatment. If you do not understand a question, please ask for help.

DEMOGRAPHICS

Last Name

First Name

Middle Initial

Social Security Number

Today's Date (dd/mm/yyyy)

Name of Your Unit during this Deployment

Date of Birth (dd/mm/yyyy)

Gender

☐ Male ☐ Female

Service Branch

- ☐ Air Force
- ☐ Army
- ☐ Coast Guard
- ☐ Marine Corps
- ☐ Navy
- ☐ GS Employee
- ☐ Other

Component

- ☐ Active Duty
- ☐ National Guard
- ☐ Reserves
- ☐ Civilian Government Employee
- ☐ Other

Pay Grade

- ☐ E1 ☐ O1
- ☐ E2 ☐ O2
- ☐ E3 ☐ O3
- ☐ E4 ☐ O4
- ☐ E5 ☐ O5
- ☐ E6 ☐ O6
- ☐ E7 ☐ O7
- ☐ E8 ☐ O8
- ☐ E9 ☐ O9
- ☐ O10

W

- ☐ W1
- ☐ W2
- ☐ W3
- ☐ W4
- ☐ W5
- ☐ Other

Date of arrival in theater (dd/mm/yyyy)

Date of departure from theater (dd/mm/yyyy)

Name of Operation:

Location of Operation. To what areas were you mainly deployed (land-based operations for more than 30 days)?
(Please mark all that apply, including the number of months spent at each location.)

- ☐ Country 1
- ☐ Country 2
- ☐ Country 3
- ☐ Country 4
- ☐ Country 5

Time at location (months)

Time at location (months)

Time at location (months)

Time at location (months)

Time at location (months)

Occupational specialty during this deployment (MOS/AOC, NEC/NOBC, or AFSC):

Combat specialty:

Current Contact Information:

Phone:

Cell:

DSN:

Email:

Address:

Point of Contact who can always reach you:

Name:

Phone:

Email:

Mailing Address:

TBI Screen – Injury Event

9.a. During this deployment, did you experience any of the following events? *(Mark all that apply)*

(1) Blast or explosion *(IED, RPG, land mine, grenade, etc.)*

(2) Vehicular accident/crash *(any vehicle, including aircraft)*

(3) Fragment wound or bullet wound above your shoulders

(4) Fall

(5) Other event *(for example, a sports injury to your head)*. Describe:

TBI Screen – Alteration in Consciousness

9.b. Did any of the following happen to you, or were you told happened to you, IMMEDIATELY after any of the event(s) you just noted in question 9.a.?

(Mark all that apply)

- (1) Lost consciousness or got "knocked out"
- (2) Felt dazed, confused, or "saw stars"
- (3) Didn't remember the event
- (4) Had a concussion
- (5) Had a head injury

Symptoms - Acute

9.c. Did any of the following problems begin or get worse after the event(s) you noted in question 9.a.?

(Mark all that apply)

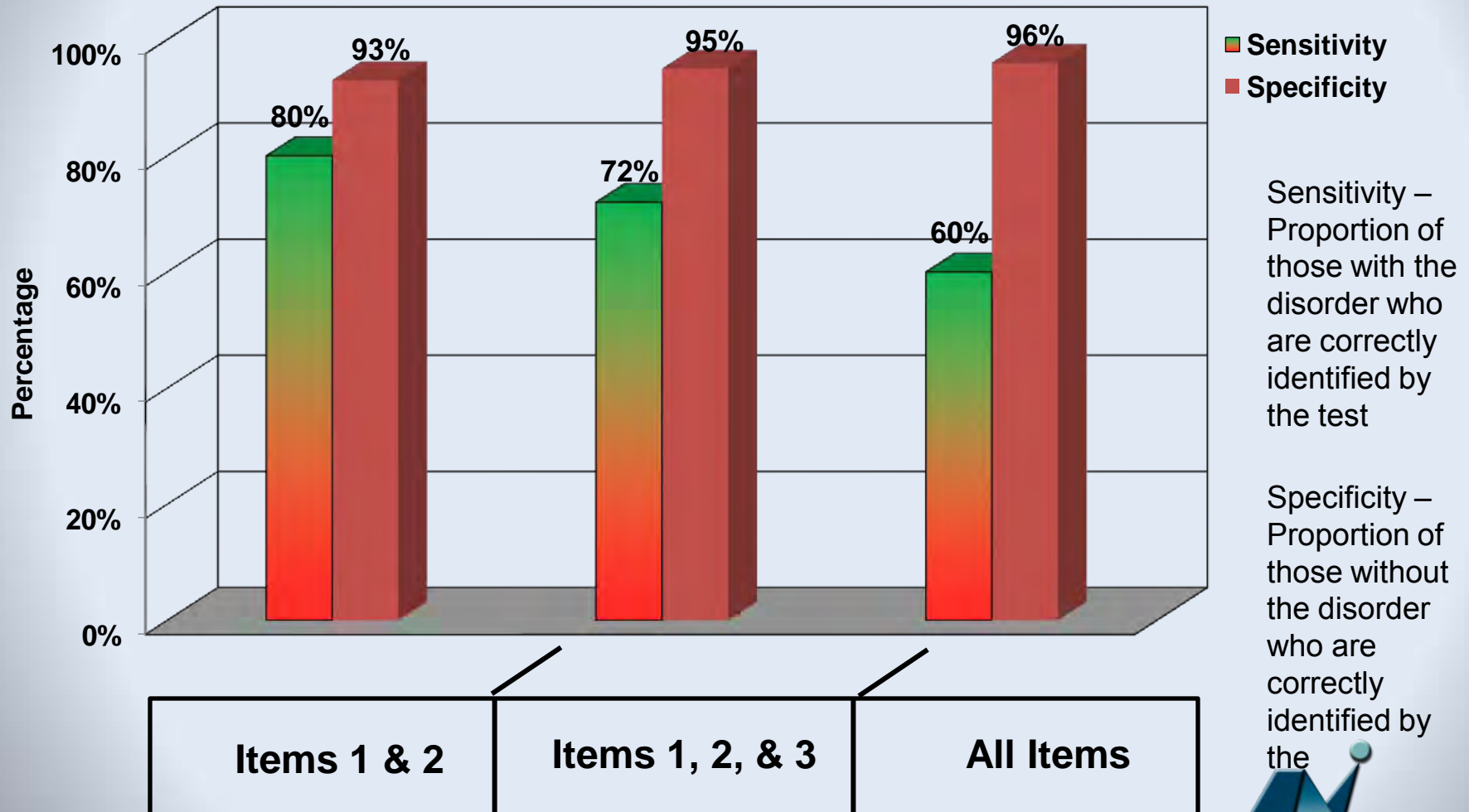
- (1) Memory problems or lapses
- (2) Balance problems or dizziness
- (3) Ringing in the ears
- (4) Sensitivity to bright light
- (5) Irritability
- (6) Headaches
- (7) Sleep problems

Symptoms - Persistent

9.d. In the past week, have you had any of the symptoms you indicated in 9.c.? *(Mark all that apply)*

- (1) Memory problems or lapses
- (2) Balance problems or dizziness
- (3) Ringing in the ears
- (4) Sensitivity to bright light
- (5) Irritability
- (6) Headaches
- (7) Sleep problems

Diagnostic Performance of the DoD TBI Screen



Study Design and Aims

- Longitudinal design (baseline at PDHA, re-assessments at 3, 6, 12 months post-baseline)
- Explore incidence, prevalence & sequelae of TBI in Active Duty Soldier population
- Explore psychometric properties of DoD TBI screening questions
- Assess functional outcomes
- Assess incidence of other health & mental health concerns

Sample

- Two groups of returning OEF or OIF Active Duty Army Soldiers
- Data for 345 participants

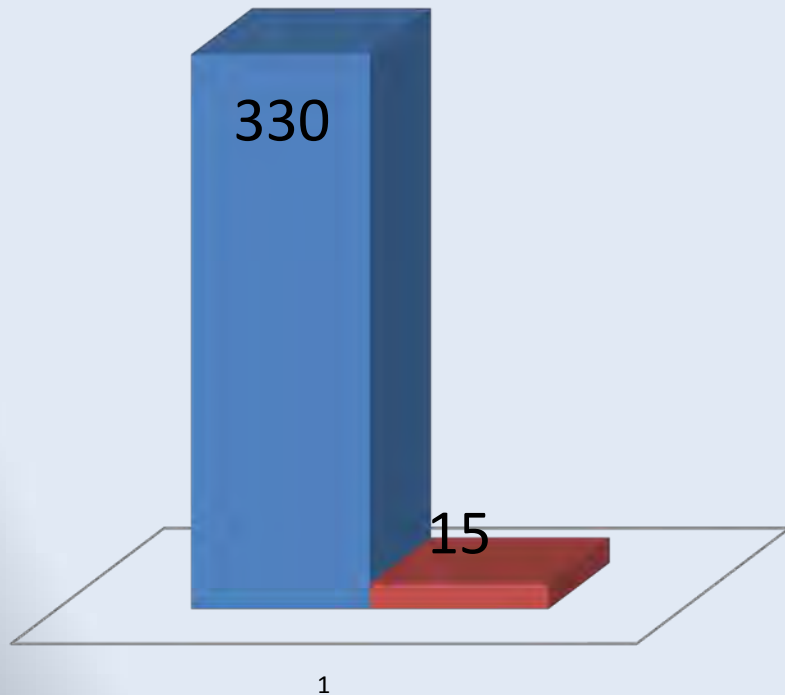
Methods to Obtain Preliminary Data

- Soldiers completed the Ohio State University Traumatic Brain Injury Identification Method (OSU TBI-ID) – structured clinical interview
- All analyses were completed using data from the OSU TBI-ID & demographics questionnaire

Demographics

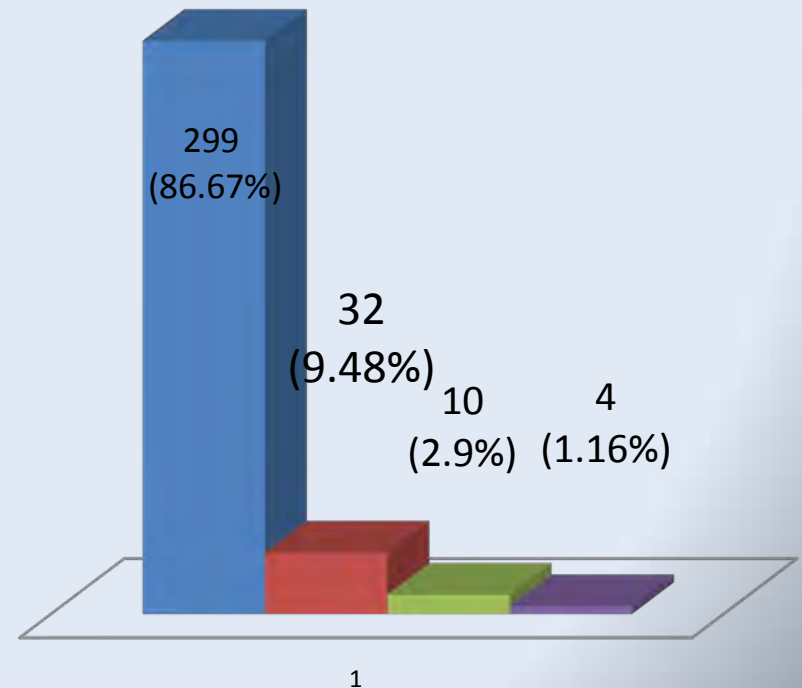
GENDER (N = 345)

■ Male ■ Female



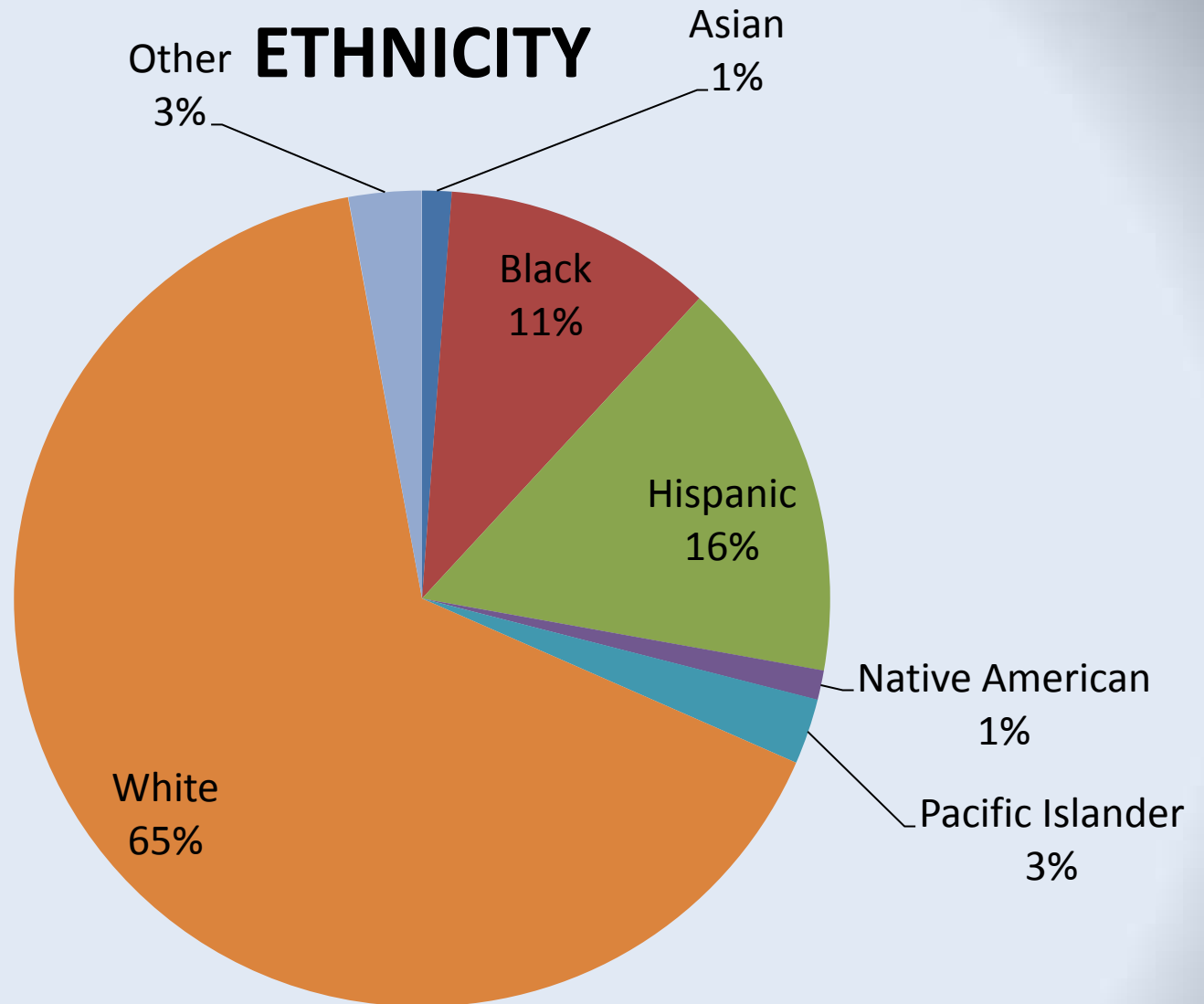
HANDEDNESS

■ Right ■ Left
■ Ambidextrous ■ Missing

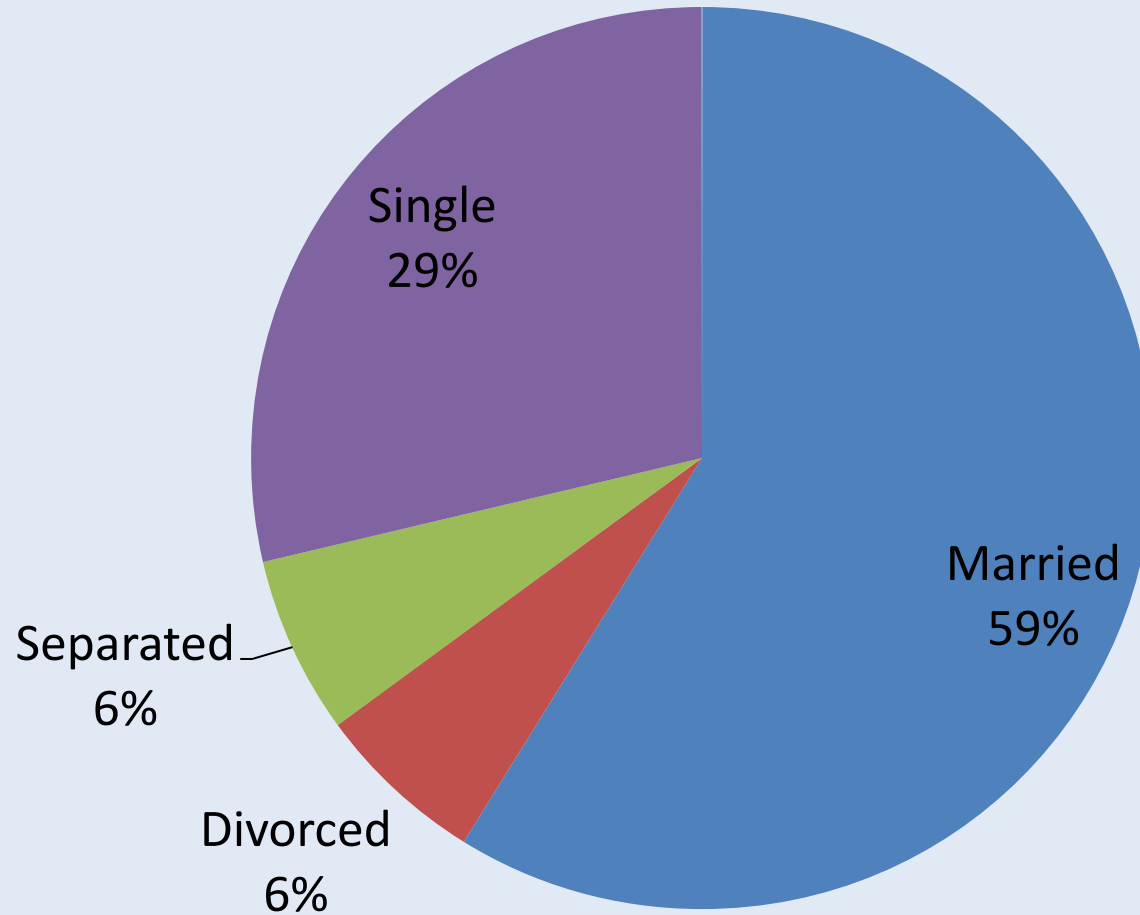


YEARS ON ACTIVE DUTY

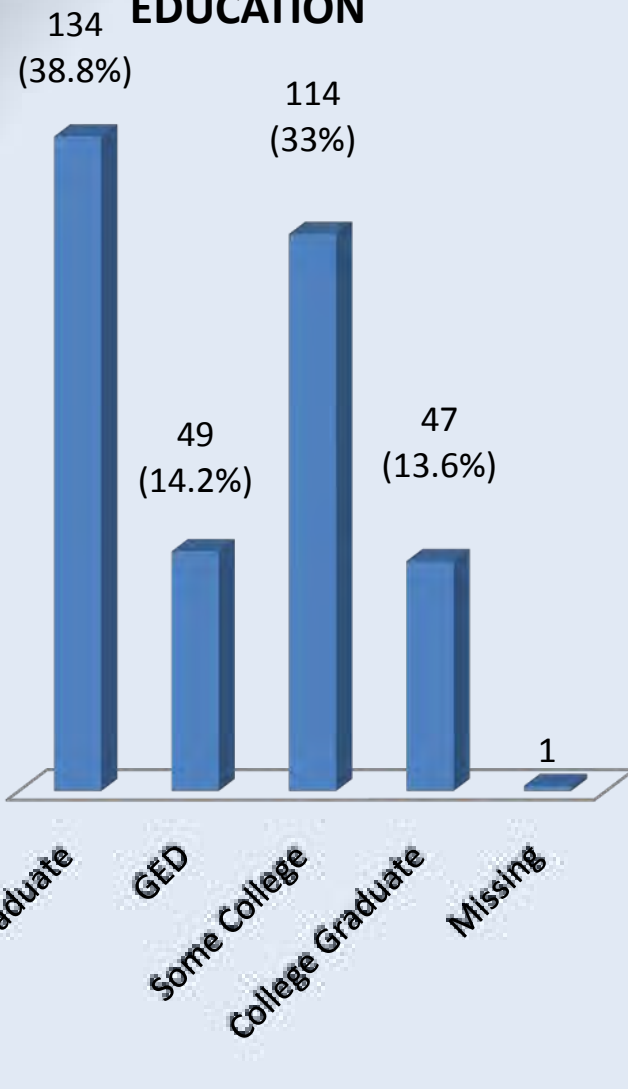
Mean	6.03
SD	4.34
Minimum	1
Maximum	22
Median	4
Mode	2



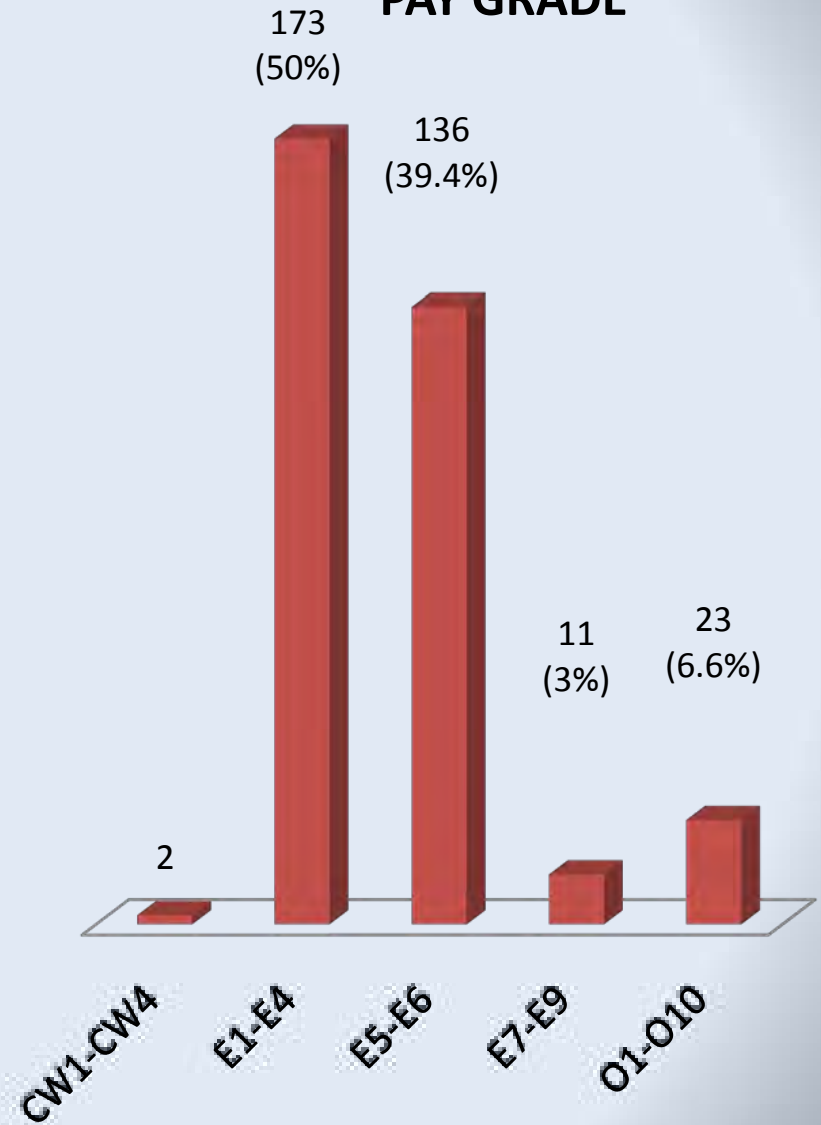
MARITAL STATUS



EDUCATION



PAY GRADE



TBI Data

- *260 Soldiers endorsed criteria for TBI*
- *A total of 622 lifetime TBIs were reported*

Mean	2.39
SD	1.66
Minimum	1
Maximum	11
Mode	1
Median	2

Deployment-Only TBI Data

252 deployment-related TBIs were recorded

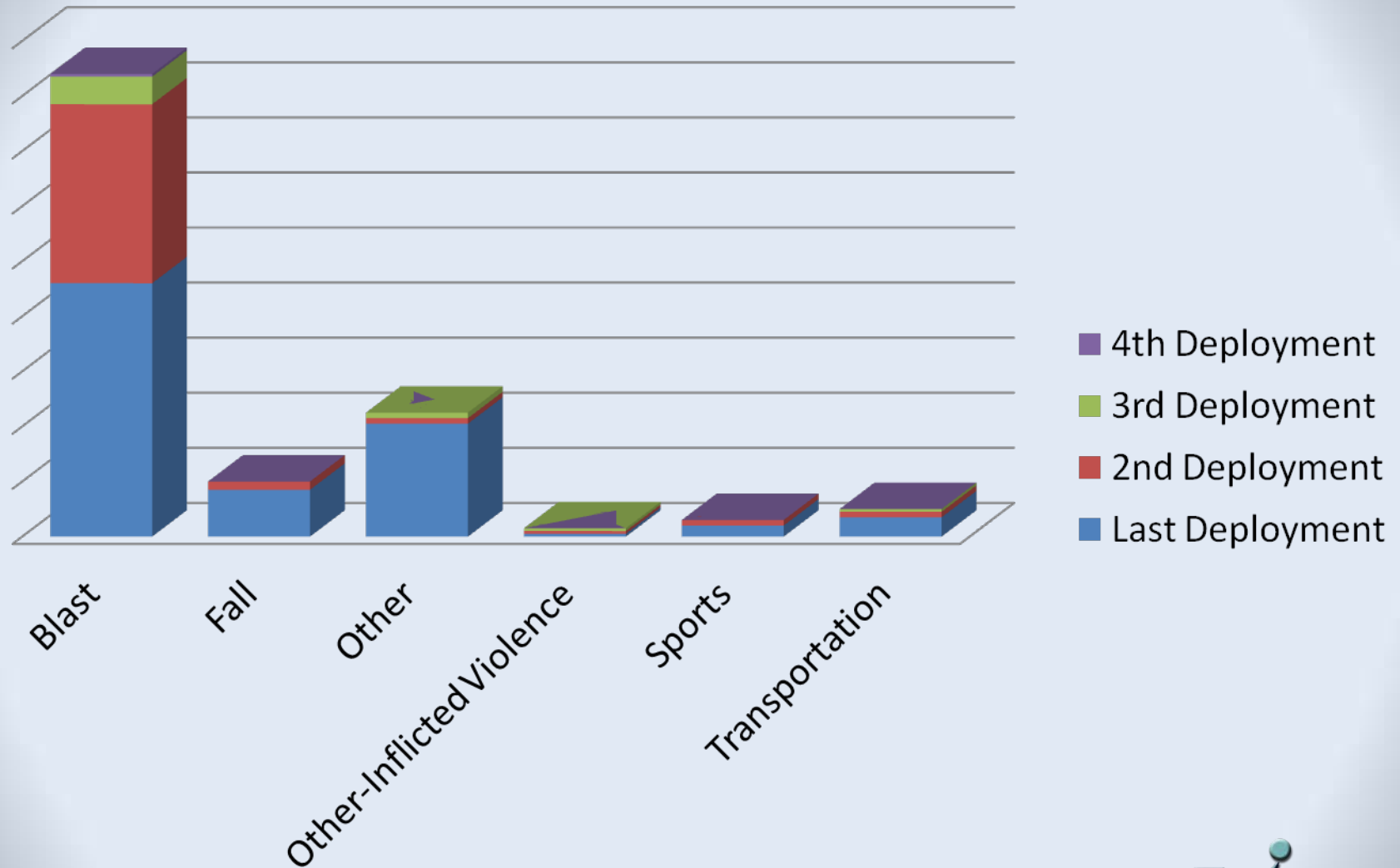
Knocked Out or LOC from Injury	N = 67 (27%)
If yes, for < 5 minutes	57
If yes, for 5 – 30 minutes	4
If yes, for > 30 minutes	0
Unable to estimate	4
Missing	2

If not knocked out,	
Did the injury cause you to become dazed and confused	182
Did you forget what happened before or after the injury?	50

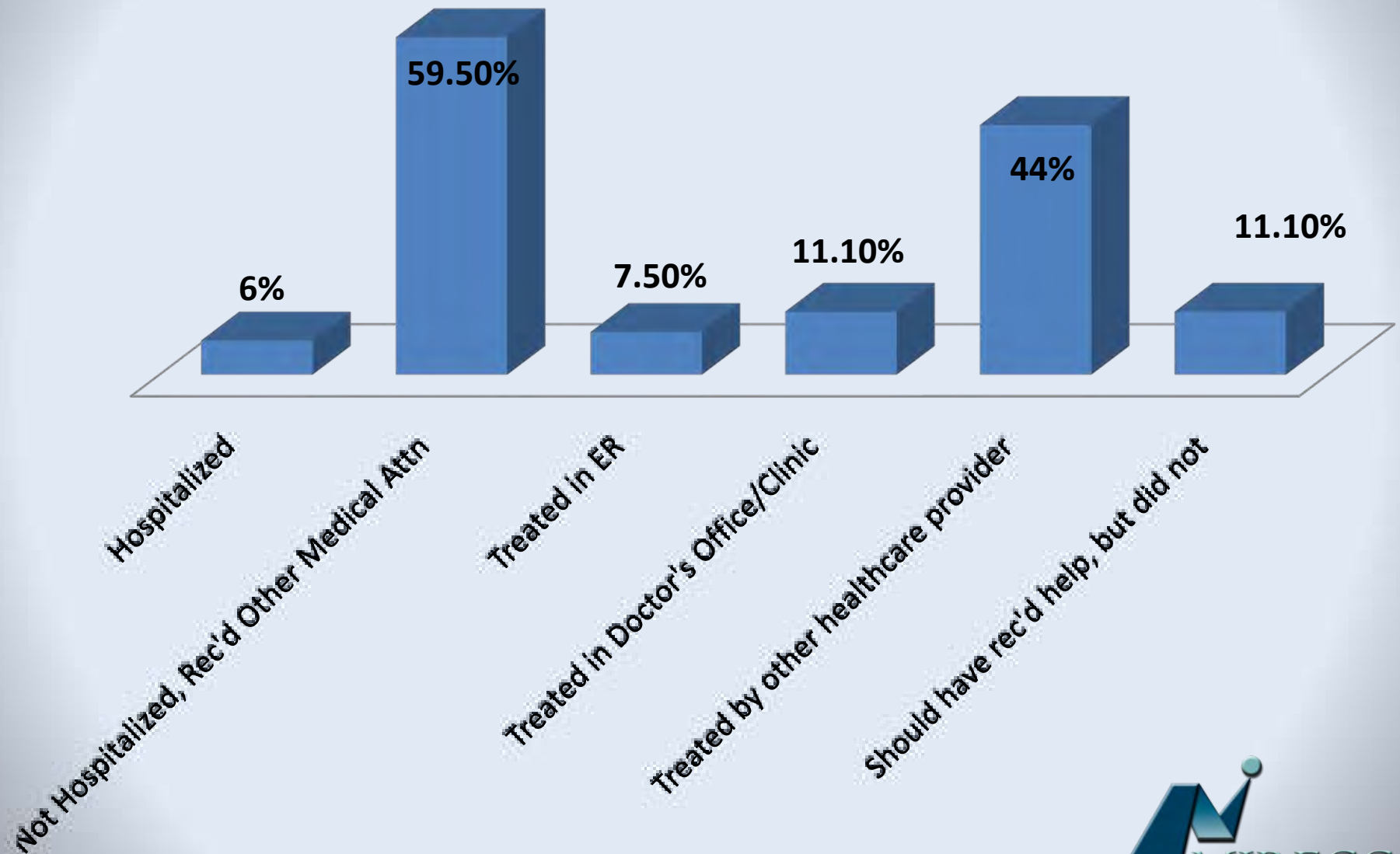
Deployment TBI	
Mean	1.44
SD	.76
Median	1.0
Mode	1.0
Max.	5.0

Deployment TBI Frequency	
1 TBI	69.4%
2 TBIs	19.7%
3 TBIs	9.2%
4 TBIs	1.2%
5 TBIs	0.6%

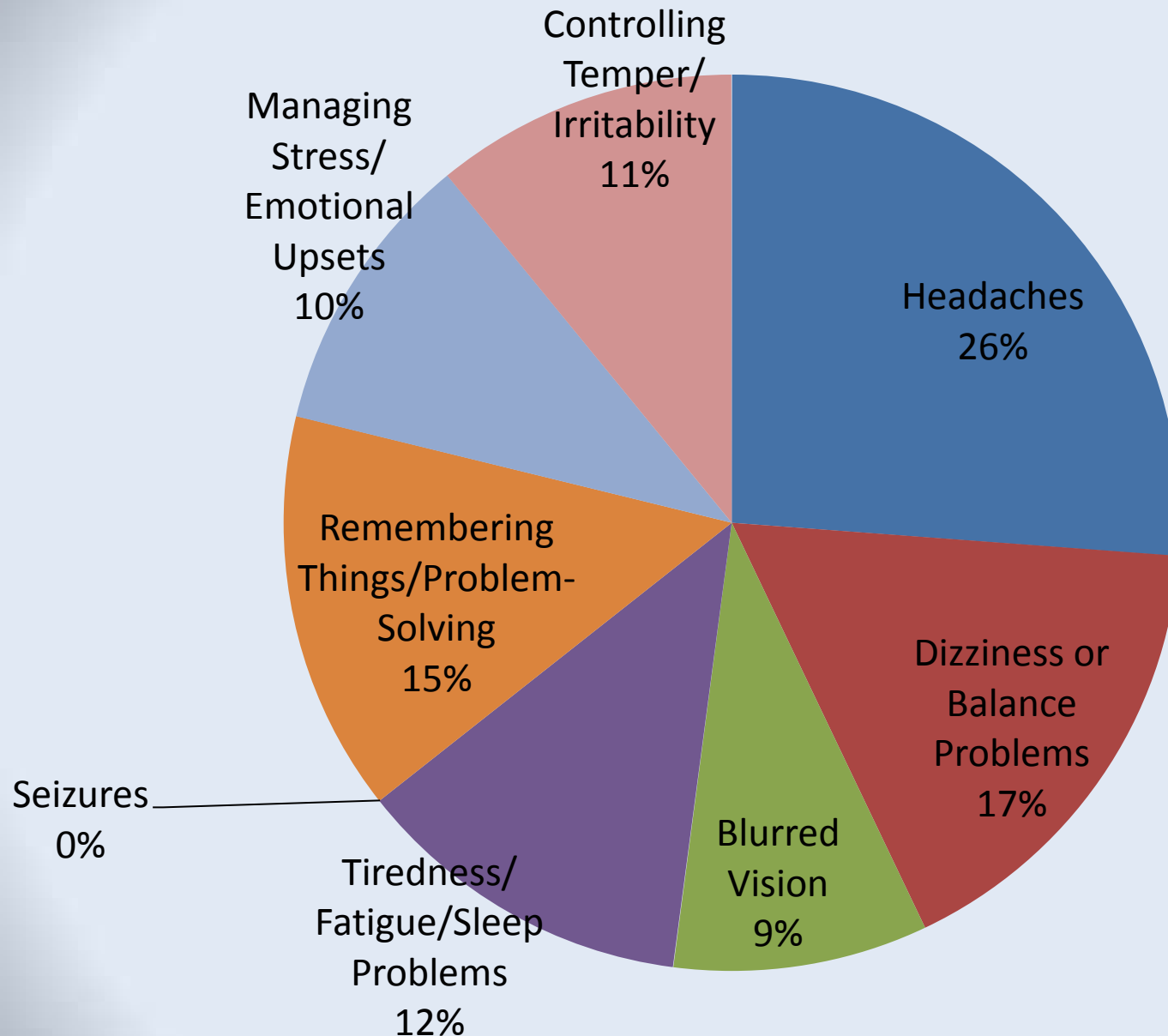
Mechanism of Injury by Deployment



Deployment-Related TBI Medical Attention

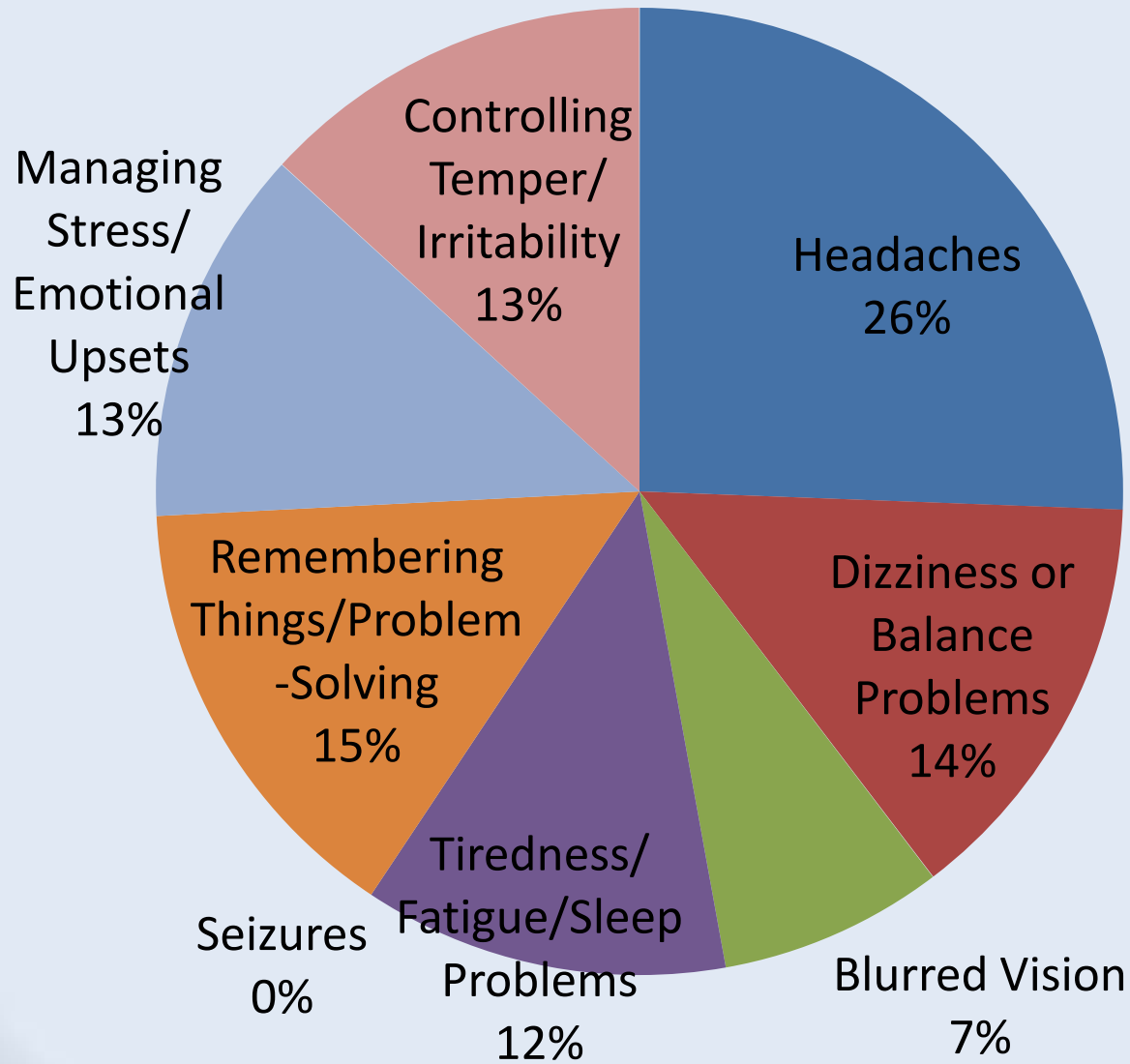


TOTAL DEPLOYMENT-RELATED mTBI SYMPTOMS (N = 252)

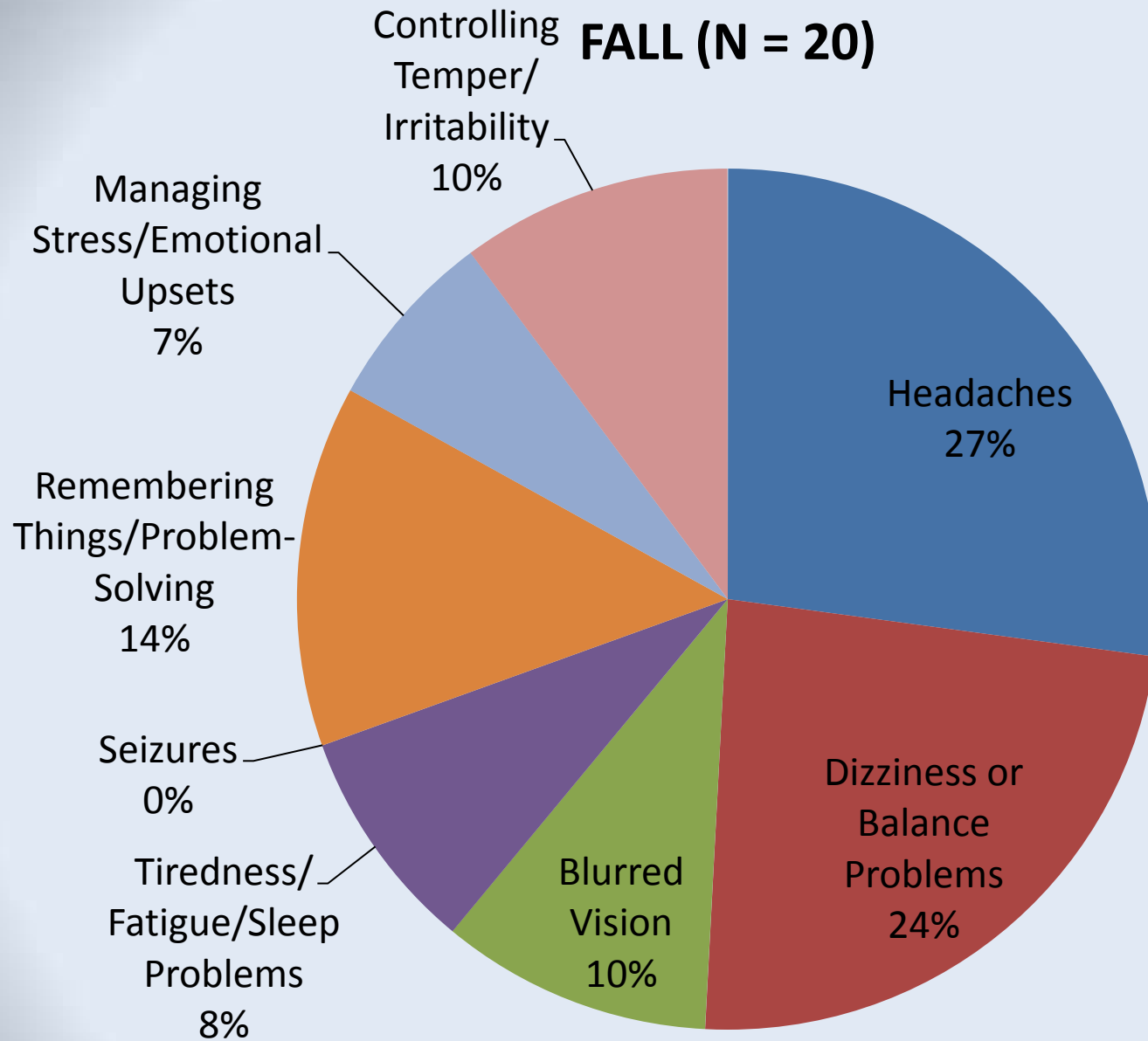


Symptoms by Mechanism of Injury

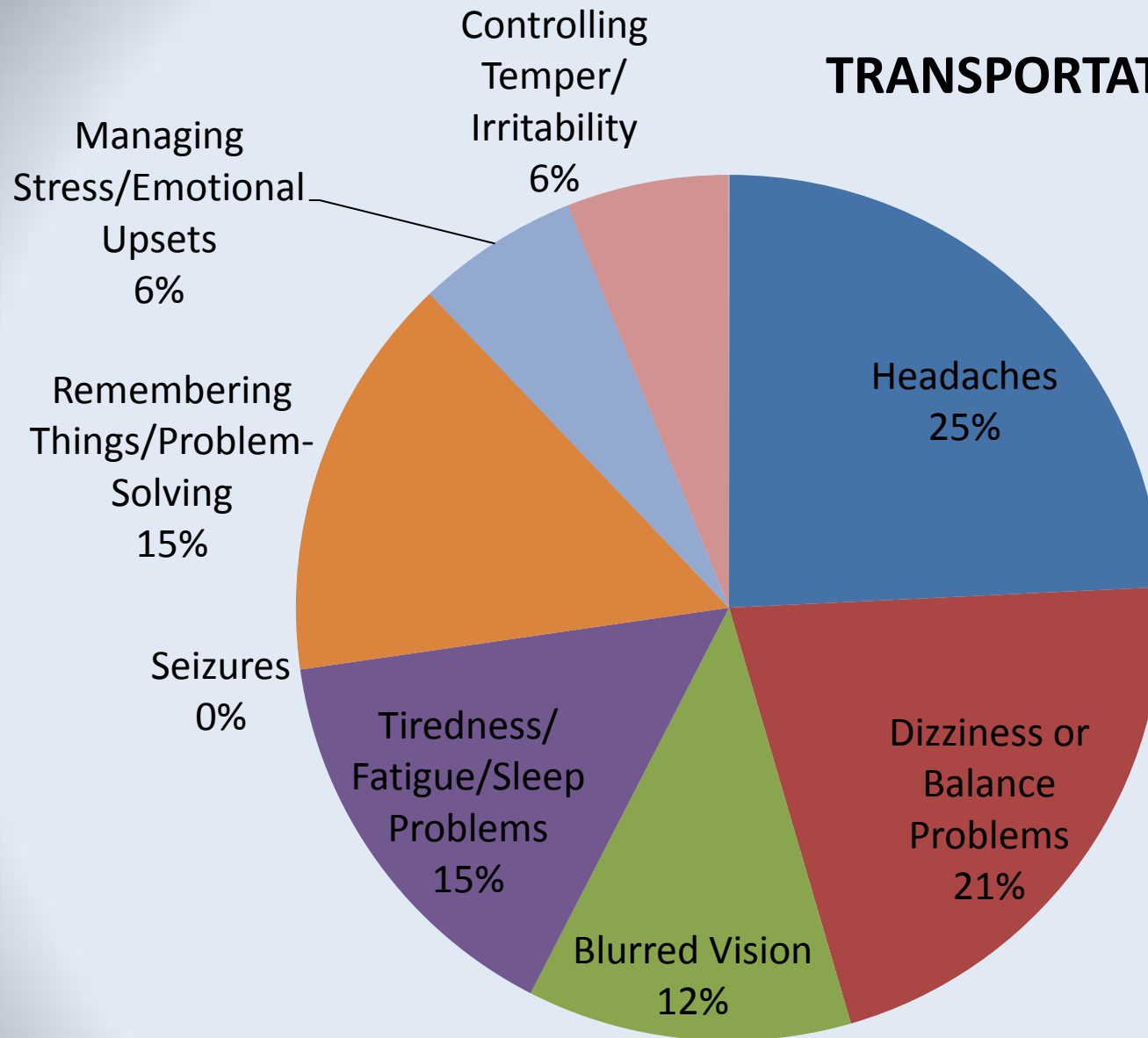
BLAST (N = 168)



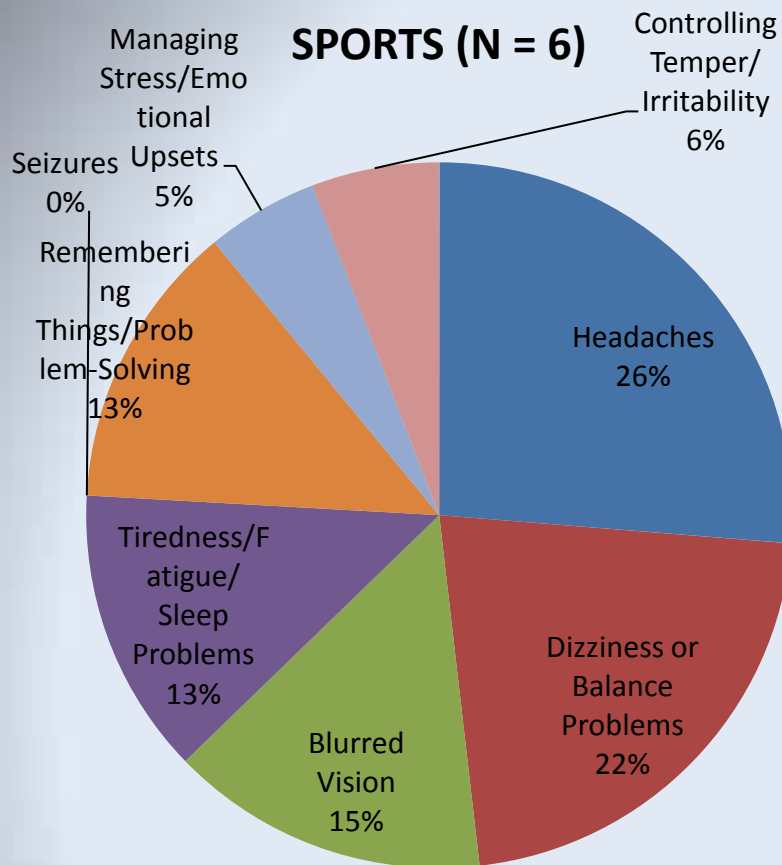
FALL (N = 20)



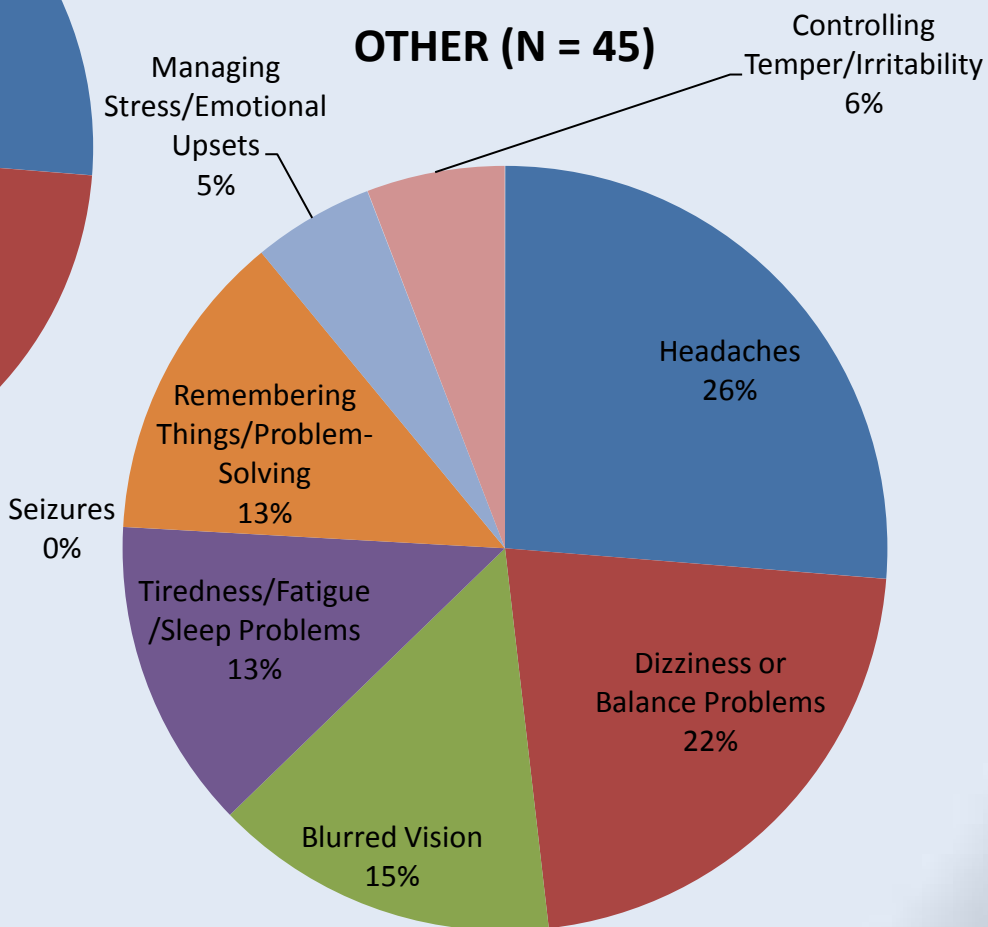
TRANSPORTATION (N = 10)



SPORTS (N = 6)



OTHER (N = 45)



TBI Screening in a VA MH Setting

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Methods

- January 2007 - Four TBI screening questions (TBI-4) were developed and added to the standard VA Eastern Colorado Health Care System (ECHCS) Mental Health Intake form
 - 1) Have you ever been hospitalized or treated in an emergency room following a head or neck injury?
 - 2) Have you ever been knocked out or unconscious following an accident or injury?
 - 3) Have you ever injured your head or neck in a car accident or from some other moving vehicle accident?
 - 4) Have you ever injured your head or neck in a fight or fall?

Methods (cont'd)

- Record review of 1,810 Veterans who were screened using the TBI-4
 - A key word search identified notes documenting psychiatric hospitalizations and suicide attempts for the year following the TBI-4 screening
 - Clinicians then reviewed and coded each note to confirm presence or absence of a suicide attempt or psychiatric hospitalization

Statistical Analyses

- Logistic regression used to model each outcome as a function of TBI-4 status
 - Initially controlled for potential confounders (i.e. sex and age)
 - If potential confounders were not significant and did not change the parameter estimate for TBI-4 status by more than 10%, they were removed
- Demographic variables were compared using t-tests and chi-square tests as appropriate.

Results - Demographics and Outcomes by TBI-4 Status (n=1,810)

Characteristic	All Subjects (n=1810)	Positive/Negative TBI-4 Criteria		p-value	Positive/Negative TBI-4 Criteria		p-value
		Yes to any N=1146 (63% of 1810)	No to all N=664		Yes to Q2 N=809 (45% of 1810)	No to Q2 N=1001	
Male	1639 (91%)	1052 (92%)	587 (88%)	0.02	765 (95%)	874 (87%)	<0.0001
Age	48.3 (12.9)	48.3 (12.6)	48.4 (13.5)	0.88	48.4 (12.6)	48.3 (13.2)	0.83
Psychiatric Hospitalizations	106 (5.9%)	78 (6.8%)	28 (4.2%)	0.02	55 (6.8%)	51 (5.1%)	0.12
Suicide Attempt	37 (2.0%)	26 (2.3%)	11 (1.7%)	0.38	23 (2.8%)	14 (1.4%)	0.03
Suicide Completion	2 (0.1%)	2 (0.2%)	0 (0%)	N/A*	1 (0.1%)	1 (0.1%)	N/A*

*Statistical significance not possible

Results - Positive TBI-4: Yes to Any Question

Outcome	Final Model Variables	Odds Ratio (95% CI)	Probability of an Event (95% CI)	p-value
Psychiatric Hospitalizations	TBI-4 Status	1.66 (1.07, 2.58)	For Positive TBI-4: 0.068 (0.055, 0.084) For Negative TBI-4: 0.042 (0.029, 0.060)	0.03
Suicide Attempts	TBI-4 Status	1.40 (0.69, 2.86)	For Positive TBI-4: 0.020 (0.013, 0.030)** For Negative TBI-4: 0.014 (0.008, 0.027)**	0.35

**Calculated for the mean age of 48 in each group

Results - Positive TBI-4: Yes to Question 2

Have you ever been knocked out or unconscious following an accident or injury?

Outcome	Final Model Variables	Odds Ratio (95% CI)	Probability of an Event (95% CI)	p-value
Psychiatric Hospitalizations	TBI-4 Status	1.36 (0.92, 2.01)	For Positive TBI-4: 0.068 (0.053, 0.088) For Negative TBI-4: 0.051 (0.039, 0.066)	0.13
Suicide Attempts	TBI-4 Status	2.10 (1.07, 4.12)	For Positive TBI-4: 0.025 (0.016, 0.039)** For Negative TBI-4: 0.012 (0.007, 0.021)**	0.03

**Calculated for the mean age of 48 in each group

Conclusions

- Those who screened positive for *risky behavior* were at increased risk for psychiatric hospitalization one year post-injury
- Those who screened positive for *TBI* were at increased risk for a suicide attempt one year post-injury
- These findings support the need for screening and assessment for TBI in all Veterans

Next steps....

TBI-4 vs. OSU TBI-ID (Gold Standard)

Response Patterns = Different
Populations?



TBI-4 Questions



Use Your Smartphone to Visit the VISN 19 MIRECC Website

Requirements:

1. Smartphone with a camera
2. QR scanning software (available for free download just look at your phones marketplace)



www.mirecc.va.gov/visn19

